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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/038,114      | 12/31/2001  | Dilip Wagle          | 361331-508          | 5391             |

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/038,114          | <b>Applicant(s)</b><br>WAGLE ET AL. |  |
|                              | <b>Examiner</b><br>Cybille Delacroix-Muirheid | <b>Art Unit</b><br>1614             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005 and 01 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Detailed Action***

The following is responsive to applicant's election received March 2, 2005.

Applicant's election of 3-carbamoyl-1-(4-methoxy-benzyl)-pyridinium; chloride with traverse is acknowledged. Since, however, applicant has not specifically argued the alleged errors in the requirement mailed Feb. 9, 2005, it is being maintained for reasons already of record.

Claims 9-15 are cancelled. Claims 1-8, 16-18 are currently pending.

No prior art was found for the elected species. Therefore, the examiner has expanded the search to non-elected species.

The previous rejection of claims 1-14 under 35 USC 103(a) over Gall 6,596,745, set forth in the office action mailed July 1, 2004 is withdrawn in view of applicant's amendment received Nov. 1, 2004 and the remarks contained therein.

***New Ground(s) of Rejection***

***Claim Rejection(s)—35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

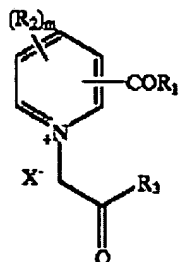
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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1. Claims 1-8, 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Sankaranarayanan US 2001/0018524 A1.

Sankaranarayanan discloses methods for managing diabetes and aging-related vascular complications. Specifically, Sankaranarayanan teaches administering to a patient an effective amount of a compound of the general formula (I):

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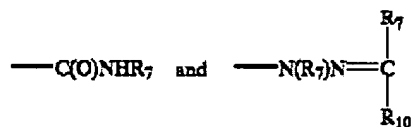


[0016] wherein

[0017]  $R_1$  is  $-R_4-R_5$  or  $-N(R_7)N(R_7)R_9$ ;

[0018]  $R_4$  is selected from the group consisting of  $-N(R_7)R_6O-$ ,  $-N(R_7)R_6N(R_7)-$ ,  $OR_6O$ , and  $-OR_6N(R_7)-$ , where  $R_6$  is alkyl;

[0019]  $R_5$  is selected from the group consisting of alkyl, aryl including heteroaryl,  $-COR_7$ ,  $SO_2R_7$ ,  $-C(S)NHR_7$ ,  $-C(NH)NHR_7$ ,  $-COR_{10}$ ,  $-C(O)NHR_7$  and



[0020] where  $R_7$  is selected from the group consisting of H, alkyl and aryl including heteroaryl provided  $R_7$  may be the same or different for  $R_1$  and  $R_3$  in the same compound;

[0021]  $R_2$  is selected from the group consisting of F, Cl, Br, I,  $OR_7$ ,  $NO_2$ , alkyl, aryl including heteroaryl, formyl, acyl,  $C(O)NR_7R_{10}$ ,  $C(O)OR_7$ ,  $NR_7R_{10}$ ,  $N=C(R_7)(R_{10})$ ,  $SR_7$ ,  $SO_2NH_2$ ,  $SO_2$  alkyl and  $SO_2$  aryl, and  $m$  is 0, 1 or 2;

[0022]  $R_3$  is selected from the group consisting of  $R_7$ ,  $OR_7$ ,  $N(R_7)(R_{10})$ ,  $N=C(R_7)(R_{10})$ ,  $N(R_7)N(R_7)(R_{10})$ ,  $N(R_7)N=C(R_7)(R_{10})$  and  $CH(R_7)C(O)R_8$  where  $R_8$  is selected from the group consisting of  $R_7$ ,  $OR_7$  and  $NR_7R_{10}$ ;

[0023]  $R_9$  is selected from the group consisting of hydrogen, alkyl, aryl including heteroaryl,  $C(O)R_{10}$ ,  $-SO_2R_{10}$ ,

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$-\text{C}(\text{S})\text{NHR}_{10}$ ,  $-\text{C}(\text{NH})\text{NH}(\text{R}_{10})$  and  $-\text{C}(\text{O})\text{NHR}_{10}$ ,  $\text{R}_{10}$  is selected for the group consisting of H, alkyl or aryl including heteroaryl and in each case may be the same or different from substituent  $\text{R}_7$ , provided  $\text{R}_{10}$  may be the same or different for  $\text{R}_1$  and  $\text{R}_3$  in the same compound;

[0024] X is selected from group consisting of a halide ion, acetate ion, perchlorate ion, sulfonate ion, oxalate ion, citrate ion, tosylate ion, maleate ion, mesylate ion, carbonate ion, sulfite ion, phosphoric hydrogen ion, phosphonate ion, phosphate ion,  $\text{BF}_4^{31}$  and  $\text{PF}_6^{31}$ ; with proviso that,

[0025] (i) when two alkyl groups are present on the same carbon or nitrogen, they may be linked together to form a cyclic structure and

[0026] (ii) the nitrogen of heteroaryl ring of  $\text{R}_{10}$ , when present, may be quaternized.

The age-related complications include retinopathy or retinal disorder. Please see paragraph [0077]; [0394]; [0395]; claim 24.

The claims are anticipated by Sankaranarayanan because Sankaranarayanan teaches administration of identical compounds to a host using applicant's claimed method steps. Therefore, a decrease in intraocular pressure or an improvement in ocular accommodation would be inherent.

### **Conclusion**

Claims 1-8, 16-18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone

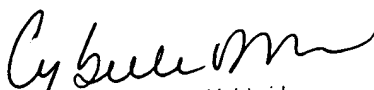
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number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

May 31, 2005

  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600